

K092176

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7602 - Phone
(714) 516-7488 - Facsimile
Wendy Garman - Contact Person

JAN 28 2010

Date Summary Prepared: July 2009

Device Name:

- Trade Name – Take 1 Advanced Rigid Tray
- Common Name – Dental Impression Material
- Classification Name – Impression Material, per 21 CFR § 872.3660

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *Take 1*

Device Description:

The device is an addition-cure vinyl polysiloxane dental impression material that is used for all crowns and bridges, edentulous, orthodontic and implant impression techniques. Take 1 Advanced Rigid Tray is a two-part, base/catalyst – paste/paste system. The product is available in a heavy body viscosity, offered in cartridge 1:1 delivery and Volume 5:1 delivery, and in 3 setting speeds: regular set, fast set and super fast set.

Intended Use of the Device:

Take 1 Advanced Rigid Tray is an addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.

Substantial Equivalence:

Take 1 Advanced Rigid Tray is substantially equivalent to another legally marketed device in the United States. Take 1 Advanced Rigid Tray functions in a manner similar to and is intended for the same use as Take 1, marketed as Take 1 Advanced and manufactured by Kerr Corporation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Kerr Corporation
C/O Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

JAN 28 2010

Re: K092176
Trade/Device Name: Take 1 Advanced Rigid Tray
Regulation Number: 21CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: January 11, 2010
Received: January 12, 2010

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 for

Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092176

Indications for Use

510(k) Number (if known):

Device Name: *Take 1 Advanced Rigid Tray*

Indications For Use:

Take 1 Advanced Rigid Tray is an addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K092176